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# Toxicological Review of Trichloroethylene: in Support of Summary Information on the Integrated Risk Information System (IRIS) (External Review Draft)

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EPA announces the release of the draft Toxicological Review of Trichloroethylene in a November 3, 2009 Federal Register Notice.

This draft assessment is provided for public review and comment. Public comments received on the Toxicological Review within 90 days after the release of the FRN (on or before February 1, 2010) will be provided to the external peer reviewers for their consideration. Any comments not received within the requested time period will be considered by EPA in their revisions.

EPA conducted a peer review of the scientific basis supporting the human health hazard and dose-response assessment of Trichloroethylene (TCE) that will appear on the Integrated Risk Information System (IRIS) database.

## Background

The draft Toxicological Review of Trichloroethylene (TCE) provides scientific support and rationale for the hazard and dose-response assessment pertaining to chronic exposure to TCE. TCE is a chlorinated solvent that has been widely used as a metal degreaser, as a chemical intermediate and extractant, and as a component of some consumer products. TCE is designated as a Hazardous Air Pollutant, is a common groundwater contaminant, and has been found at more than 1,500 hazardous waste sites. TCE enters the atmosphere from vapor degreasing operations or volatilization from contaminated soils, surface waters via direct discharges, and groundwater through leaching from disposal operations and hazardous waste sites. In addition, TCE can be released to indoor air from the use of TCE-containing consumer products, volatilization from water supplies, and vapor intrusion through walls and floors from contaminated soil and groundwater.

History/Chronology

- Aug 2001 EPA released an External review draft Trichloroethylene Health Risk Assessment: Synthesis and Characterization for public review and comment.
- Dec 2002 EPA's Science Advisory Board released an independent peer review report Review of Draft Trichloroethylene Health Risk Assessment: Synthesis and Characterization: An EPA Science Advisory Board Report (PDF, 83 pp, 376 KB, about PDF).

- Feb 2004 EPA hosted a Symposium on New Scientific Research Related to the Health Effects of Trichloroethylene held in Washington, DC.
- Sep 2004 The National Academy of Science (NAS) initiated the project "Assessing the Human Health Risks of Trichloroethylene: Key Scientific Issues" under sponsorship of EPA and other federal agencies.
- Feb 2005 EPA submitted four TCE issue papers on key scientific issues to the NAS.
- July 2006 The National Academy of Science (NAS) released the report Assessing the Human Health Risks of Trichloroethylene: Key Scientific Issues Consultation.
- Sep 2009 EPA hosted an interagency science discussion on the review of the draft Toxicological Review of Trichloroethylene.
- Oct 2009 EPA Science Advisory Board (SAB) releases October 22, 2009 Federal Register Notice requesting nominations of experts for the SAB TCE Review Panel.
- Nov 2009 EPA releases the External Review Draft for public review and comment.

#### Next Steps

Following external peer review the assessment will be revised taking into consideration external peer review and public comments, will undergo a final EPA internal review and a review by and science discussion with other federal agencies and White House offices, and will be posted to the IRIS database.

#### Downloads/ Related Links

This download(s) is distributed solely for the purpose of pre-dissemination peer review under applicable information quality quidelines. It has not been formally disseminated by EPA. It does not represent and should not be construed to represent any Agency determination or policy.

- Toxicological Review of Trichloroethylene (PDF) (1109 pp, 7 MB, about PDF)
- Toxicological Review of Trichloroethylene: Appendices (All) (PDF) (1221 pp, 9 MB, about PDF)
- Charge to External Peer Reviewers (PDF) (5 pp, 153 KB, about PDF)

- TR of TCE: Chapter 1. Introduction (PDF) (2 pp, 132 KB, about PDF)
  TR of TCE: Chapter 2. Exposure Characterization (PDF) (25 pp, 441 KB, about PDF)
- TR of TCE: Chapter 3. Toxicokinetics (PDF) (139 pp, 1 MB, about PDF)
- TR of TCE: Chapter 4. Hazard Characterization (PDF) (330 pp, 2 MB, about PDF)
- TR of TCE: Chapter 4. Hazard Characterization (Continued) (PDF) (291 pp, 3 MB, about PDF)
- TR of TCE: Chapter 5. Dose-Response Assessment (PDF) (153 pp, 2 MB, about PDF)
- TR of TCE: Chapter 6. Major Conclusions in the Characterization of Hazard and Dose Response (PDF) (42 pp, 400 KB, about PDF)
- TR of TCE: References (PDF) (83 pp, 604 KB, about PDF)
  TR of TCE: Appendix A: PBPK Modeling of TCE and Metabolites Detailed Methods and Results (PDF) (116 pp, 1 MB, about PDF)
  TR of TCE: Appendix B: Systematic Review of Epidemiologic Studies on Cancer and
- Trichloroethylene (TCE) Exposure (PDF) (365 pp, 2 MB, about PDF)
- TR of TCE: Appendix C: Meta-Analysis of Cancer Results from Epidemiological Studies (PDF) (68 pp, 664 KB, about PDF)
- TR of TCE: Appendix D: Neurological Effects of Trichloroethylene (PDF) (133 pp, 999 KB, about PDF)
- TR of TCE: Appendix E: Analysis of Liver and Coexposure Issues for the TCE Toxicological Review (PDF) (445 pp, 2 MB, about PDF)
- TR of TCE: Appendix F: TCE Noncancer Dose-Response Analyses (PDF) (45 pp,
- 686 KB, <u>about PDF</u>)
  TR of TCE: Appendix G: TCE Cancer Dose-Response Analyses with Rodent Cancer

- Bioassay Data (PDF) (43 pp, 1 MB, about PDF)
- TR of TCE: Appendix H: Lifetable Analysis and Weighted Linear Regression Based on Results from Charbotel Et Al. (2006) (PDF) (6 pp, 251 KB, about PDF)
- Appendix Linked Files (Zip, 130 Mb)

### Additional Information

Comments on the assessment may be submitted and reviewed using the <u>e-Government</u> <u>Regulations.gov</u> Web site. From the site, select <u>Environmental Protection Agency</u> and the key word <u>EPA- HQ-ORD-2009-0791</u> (for the docket ID).

Instructions for accessing supplementary files to Appendices A, F, and G.

- (1) Download "Appendix\_linked\_files.zip" file.
- (2) "Extract" files using Microsoft Windows or equivalent decompression software, creating a folder named "Appendix.linked.files"
- (3) Move the folder "Appendix.linked.files" to the same directory where the PDF file for Appendix A, F, or G is located.
- (4) Open the PDF file for Appendix A, F, or G using Adobe Acrobat Reader. To open the supplementary files, click on the appropriate links.

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